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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,289	08/10/2000	Volker Landschutze	514413-3834	7068

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EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/636,289

Applicant(s)

LANDSCHUTZE, VOLKER

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 9 May 2003 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 March 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 24 March 2003 have overcome the objection to claim 29 and the indefiniteness rejection of newly cancelled claim 30.

Claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 8, 10, and dependents are indefinite in their recitation of "one or more foreign nucleic acid molecules, wherein the presence and/or expression of the one or more nucleic acid molecules leads to a decrease in the activity of at least one GBSSI protein and at least one BE protein", as recited in claim 2, for example. It is unclear whether a single nucleic acid molecule that inhibits the activity of both GBSSI and BE is intended, or whether two nucleic acid molecules which each inhibit one of GBSSI and BE are intended.

Claim 7 is indefinite for depending upon newly cancelled claim 6.

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Claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on the top of page 3 of the last Office action.

Claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleic acid constructs comprising at least 1330 base pairs of the potato GBSSI gene and the entire coding sequence of the potato BEI gene, each in antisense orientation with respect to its own promoter, for the reduction of GBSSI activity and BEI activity in potato; does not reasonably provide enablement for claims broadly drawn to plant transformation with a single gene encoding any product which somehow reduces the expression or activity of both GBSSI and BEI, genes which encode or reduce the expression of any type of BE (claim 4), a single gene encoding both GBSSI and BE (claim 1, part a), nucleic acid molecules encoding a multitude of ribozymes thereto or comprising a multitude of in vivo-produced mutants thereof, or nucleic acid molecules comprising a multitude of fragments of the protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 3, bottom paragraph of the last Office action.

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Claims 1, 12, 15, and 29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Flipse et al, as stated on page 4 of the last Office action for claims 1, 3, 5-6, 12-15, 19, 21-24 and 29.

Claims 1-4, 7-12, 15, 19, 22-24, 29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ek et al (U.S. 6,169,226 filed 29 May 1998) taken with Visser et al and Safford et al, in view of Kossman et al, as stated on page 4 of the last Office action for claims 1-15, 19-24 and 29-32.

No claim is allowed.

Applicant's arguments filed 24 March 2003 have been fully considered but they are not persuasive.

Applicant urges that the rejections under 35 USC 112, first and second paragraphs, have been overcome by the amendments of 24 March 2003.

The Examiner notes that the amendments of 24 March 2003, while specifying that potato is the plant to be transformed, and that potato enzymes are to be inhibited following transformation, do not address the other issues raised by the Examiner. See the restatement of the indefiniteness rejection above, regarding the dual interpretation of the claims as reading on either two single sequences which each inhibits one enzyme, wherein the presence of both sequences inhibits both enzymes; or wherein the claims alternately read on a single sequence which somehow inhibits the activity of two different enzymes simultaneously.

Regarding the written description rejection, the Examiner maintains that the claims are broadly drawn to a multitude of sequences which somehow reduce the

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activity of GBSSI and/or BE enzymes, wherein said sequences encompass antisense RNA-encoding molecules of any source and sequence, ribozymes of any source and sequence, single sequences which somehow inhibit both GBSSI and BE activity simultaneously, etc. Applicant has not described this broad genus with a representative number and type of species, as discussed above.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Regarding the enablement rejection, see the broad interpretation of the claims as recited above, and the unpredictability and lack of guidance as set forth in the previous Office actions.

Applicant urges that the amended claims are not anticipated by Flipse et al. The Examiner maintains that amended claim 1 does not specify that two DNA molecules are introduced, each of which inhibits one of GBSSI or BEI. Instead, the preamble of claim 1 merely states that the genetic modification "**comprises** [emphasis added] the introduction of one or more nucleic acid molecules", and claim 1, part (a) merely recites that this DNA molecule may encompass a single DNA molecule which encodes at least one antisense RNA which decreases the expression of endogenous genes encoding GBSSI "**and/or** BEI" [emphasis added]. Thus, Flipse et al anticipate the claimed invention in their teaching of potato transformation with a single foreign DNA molecule encoding an antisense BEI sequence, wherein the presence of the waxy mutation would also result in the inhibition of the GBSSI protein, as stated previously. The open language of claim 1, indicating that the genetic modification "comprises" the introduction of a single foreign nucleic acid molecule, also allows for the genetic modification to further comprise a mutation in the GBSSI gene as taught by the reference.

Applicant urges that the obviousness rejection is improper, given the lack of motivation found in the prior art to substitute the BEI enzyme for the BEII enzyme, and the lack of a reasonable expectation of success set forth by the cited references.

The Examiner maintains that Ek et al suggest the use of the BEI gene, as stated on page 13 of the first Office action mailed 21 May 2002. Furthermore, it is noted that many of the claims, including claims 2-4, do not specify the type of BE to be inhibited.

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Furthermore, it is noted that Applicant's allegedly unexpected results, namely the successful alteration of starch branching, phosphate content, and gelatinization temperature, depend upon potato plant transformation with an almost full-length antisense construct corresponding to the potato GBSSI gene, and with a full-length antisense construct to the potato BEI gene. However, the claims are not so limited regarding the particular inhibitory sequence(s) used, as discussed above. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 27, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

